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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. BC1018 US CIP 11/28/2001 09/997,664 Arie Ben-Bassat 5764 EXAMINER 23906 7590 11/26/2003 E I DU PONT DE NEMOURS AND COMPANY STEADMAN, DAVID J LEGAL PATENT RECORDS CENTER ART UNIT PAPER NUMBER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE 1652

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

		Anglic	ation No.	Applicant(s)		
		09/997		BEN-BASSAT ET	г лі	
Office Action Summary		Exami	<u></u>	Art Unit	T	
	·		J Steadman	1652		
The MAILING DATE of this communication appe Period for Reply					ddress	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1)	Responsive to communication(s) f	iled on				
2a) <u></u> □	This action is FINAL .	2b)⊠ This action is	s non-final.			
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
5) 6) 7)	4a) Of the above claim(s) is/are withdrawn from consideration. 5) □ Claim(s) is/are allowed. 6) □ Claim(s) is/are rejected. 7) □ Claim(s) is/are objected to. 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.					
Application Papers						
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 						
Priority under 35 U.S.C. §§ 119 and 120						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. The translation of the foreign language provisional application has been received. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. 						
Attachmen	nt(s)					
2) Notic	ce of References Cited (PTO-892) be of Draftsperson's Patent Drawing Review mation Disclosure Statement(s) (PTO-1449)	•		Summary (PTO-413) Paper No Informal Patent Application (PT		

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DETAILED ACTION

Status of the Application

- [1] Claims 1-20 are pending in the application.
- [2] Receipt of information disclosure statements filed March 20, 2002, June 11, 2002, and October 18, 2002 is acknowledged. The information disclosure statement filed March 20, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office.
- [3] Applicants' claim to domestic priority under 35 U.S.C. 121 in the first of the specification and the application data sheet is acknowledged. However, the status of the nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.______" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.
- [4] Receipt of a sequence listing in computer readable form and paper copy is acknowledged. However, the examiner can find no statement that the computer readable form and paper copy of the sequence listing are identical. Applicants are requested to submit this statement.

Election/Restrictions

[5] Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claim(s) 1-2, 5-8, 11, and 18, drawn to an isolated nucleic acid fragment of SEQ ID NO:113, a plasmid, and a transformed host cell, classified in class 435, subclass 252.3.
- II. Claim(s) 1-2, 5-8, and 11, drawn to an isolated nucleic acid fragment of SEQ ID NO:114 and a transformed host cell, classified in class 435, subclass 252.3.
- III. Claim(s) 1-2, 5-8, and 11, drawn to an isolated nucleic acid fragment of SEQ ID NO:115 and a transformed host cell, classified in class 435, subclass 252.3.
- IV. Claim(s) 3-4, drawn to a polypeptide of SEQ ID NO:116, classified in class 435, subclass 194.
- V. Claim(s) 3-4, drawn to a polypeptide of SEQ ID NO:117, classified in class 530, subclass 350.
- VI. Claim(s) 9-10, drawn to a method of obtaining a nucleic acid fragment by hybridization or amplification using the polynucleotide of SEQ ID NO:113, classified in class 435, subclass 6.
- VII. Claim(s) 9-10, drawn to a method of obtaining a nucleic acid fragment by hybridization or amplification using the polynucleotide of SEQ ID NO:114, classified in class 435, subclass 6.
- VIII. Claim(s) 9-10, drawn to a method of obtaining a nucleic acid fragment by hybridization or amplification using the polynucleotide of SEQ ID NO:115, classified in class 435, subclass 6.

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- IX. Claim(s) 12-17 and 19-20, drawn to a method for the production of parahydroxybenzoate, classified in class 435, subclass 146.
- [6] The inventions are distinct, each from the other because:
- Inventions I and II or III are related as combination (SEQ ID NO:113) and subcombination (SEQ ID NO:114 or 115). Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination and subcombination are separately patentable as evidenced by claims 1-2. The subcombination has separate utility such as specifically encoding the polypeptide of SEQ ID NO:116 or SEQ ID NO:117.
- [8] Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case invention II has separate utility such as encoding SEQ ID NO:116. See MPEP § 806.05(d).
- [9] The polypeptides of Inventions IV-V are distinct as they each have different amino acid sequences and different functions and neither of the polypeptides would render the other obvious to one of ordinary skill in the art.
- [10] The methods of Inventions VI-IX are independent as they comprise different steps, utilize different products, and/or yield different results.

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- [11] The nucleic acids of Inventions I-III and the polypeptides of Groups IV-V each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The nucleic acids of Inventions I-III have other utility besides encoding polypeptides such as being used as a hybridization probe or PCR template and the polypeptides of Inventions IV-V can be made by another method such as chemical synthesis.
- The nucleic acids and host cells of Inventions I-III and the methods of Inventions VI-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Inventions I-III can be used for polypeptide expression and methods of obtaining nucleic acids by chemical synthesis are known the prior art and methods of making para-hydroxybenzoate are known in the prior art (see paragraphs [0004] and [0006] of the instant specification).
- [13] The polypeptides of Inventions IV-V and the methods of Inventions VI-IX are unrelated as the methods of Inventions VI-IX neither make nor use the polypeptides of Inventions VI-IX.
- [14] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of Inventions I-IX are independent or distinct, thus satisfying the first criterion for a proper

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restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and sequence search for each Invention and thus, co-examination of Inventions I-IX would place a serious burden on the examiner.

Rejoinder

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an

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otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

- [16] Claims 1-11 will be examined only to the extent the claims read on the elected subject matter.
- [17] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- [18] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

Patent Examiner

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DAVID STEAMAN

PATENT EXAMINER